

§ 892.1760

(b) *Classification*. Class II.

§ 892.1760 Diagnostic x-ray tube housing assembly.

(a) *Identification*. A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

§ 892.1770 Diagnostic x-ray tube mount.

(a) *Identification*. A diagnostic x-ray tube mount is a device intended to support and to position the diagnostic x-ray tube housing assembly for a medical radiographic procedure.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

§ 892.1820 Pneumoencephalographic chair.

(a) *Identification*. A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).

(b) *Classification*. Class II.

§ 892.1830 Radiologic patient cradle.

(a) *Identification*. A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

21 CFR Ch. I (4–1–11 Edition)

subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

§ 892.1840 Radiographic film.

(a) *Identification*. Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 66 FR 38819, July 25, 2001]

§ 892.1850 Radiographic film cassette.

(a) *Identification*. A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.

(b) *Classification*. Class II.

§ 892.1860 Radiographic film/cassette changer.

(a) *Identification*. A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.

(b) *Classification*. Class II.

§ 892.1870 Radiographic film/cassette changer programmer.

(a) *Identification*. A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.

(b) *Classification*. Class II.

§ 892.1880 Wall-mounted radiographic cassette holder.

(a) *Identification*. A wall-mounted radiographic cassette holder is a device that is a support intended to hold and